AUG 2 7 2001

K011886

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. Submitter's name, address, telephone number, initial importer, contact person

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjukuku Monolis Nishi-Shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration Number :	810047
Address, Phone and Fax of R & D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-2891 FAX 81-426-46-5613

2. Initial Importer

Name: Address:	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL 516-844-5688 FAX 516-844-5416

3. Name of Contact Person

Name:	Laura Storms-Tyler Director, Regulatory affairs, Olympus America Inc.
Address, Phone and Fax:	Two Corporate Center Drive Melville, NY 11747-3157 TEL 516-844-5688 FAX 516-844-5416

B. Device Name, Common Name

1. Common/Usual Name

Diagnostic Ultrasound System with Accessories

2. Device Name

- OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER
- EUS EXERA Ultrasonic Gastrovideoscope OLYMPUS GF TYPE UM160
- Ultrasonic Probes OLYMPUS UM-DP12/20-35R

3.Classification Name

	FR Number	Product Code	Class
Endoscope and accessories	876.1500	KOG	II
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO	II
Diagnostic Ultrasound Transducer	892.1570	ITX	II

C. Identification of the predicate or legally marketed device

The following devices information demonstrates that this device is substantially equivalent to a legally marketed, predicate medical device.

1. Ultrasound System

Device Name	#K
Olympus EU-M30 Endoscopic Ultrasound Center	K951994

2. Ultrasonic Gastrovideoscope and Probes

Device Name	#K
Olympus GF TYPE UM130 Ultrasound Gastrovideoscope	K971660
Olympus UM-2R/3R Ultrasonic Probes and associated ancillary equipment for GI	K944610
Olympus UM-2R/ 3R Ultrasonic Probes and associated ancillary equipment (for bronchial use)	K982323
Olympus UM-2R/3R Ultrasonic Probes and associated ancillary equipment (for urinary tract)	K982610
Olympus UM-2R/3R Ultrasonic Probe and associated ancillary equipment (Ob/Gyn)	K001203

D. Device Description

1. Summary

The combination of OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER, Ultrasonic Gastrovideoscope OLYMPUS GF TYPE UM160, and Ultrasonic probe OLYMPUS UM-DP12/20-35R makes a endoscopic ultrasound imaging system used to acquire and to display high-resolution and high-penetration, real-time ultrasound B-mode images.

2. Design

The EU-M60 is designed to comply with the standards listed below.

IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
IEC 60601-2-18
CISPR11

3. Materials

The material of the distal portion for MAJ-356RJ outer sheath of OLYMPUS UM-DP 12/20-35R Ultrasonic Probes is a new patient-contacting material. The biocompatibility test reports of the new material show that the new material is safe for its intended use.

E. Intended Use:

The intended uses of the EU-M60, as defined by FDA guidance documents, are:

Transesophageal	Transrectal
Transvaginal	Transurethral
Other 1)Gastrointestinal tract, biliary, pancreatic duct and the surrounding Organs 2)Intraluminal ultrasound for upper airways and tracheobronchial tree 3)Urinary tract 4)Female reproductive tract	

F. Technological Characteristics:

This device operates identically to the predicate devices in that the transducer of the endoscope or the ultrasonic probe that is inserted into the body cavity mechanically scans the targeted site. The piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images.

Technological Characteristics of this device is identical to the predicated devices identified in item C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2001

Ms. Laura Storms-Tyler
Director, Regulatory Affairs & Quality Assurance
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K011886
Trade Name: Olympus EU-M60 EUS Exera Endoscopic Ultrasound Center
Regulatory Class: II/21 CFR 876.1500
Product Code: 78 KOG
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: June 15, 2001
Received: June 18, 2001

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Olympus EU-M60 EUS Exera Endoscopic Ultrasound Center as described in your premarket notification:

Transducer Model Number

GF TYPE UM160
UM-DP12/20-35R
UM-2R/3R
GF UM130

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531

and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

4.3.1 Indications for Use Form for
OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	**Mode** of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N								
Transrectal		N								
Transvaginal		N								
Transurethral		N								
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Note1		N								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note1: Specification for "Other" :

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.

Intraluminal ultrasound for upper airways and tracheobronchial tree

Urinary tract

Female reproductive tract:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011886

4.3.2 Indications for Use Form for
EUS EXERA Ultrasonic Gastrovideoscope OLYMPUS GF TYPE UM160

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	**Mode** of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N								
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Note1		N								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Note1: Specification for "Other"
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011886

4.3.3 Indications for Use Form for OLYMPUS UM-DP12/20-35R Ultrasonic Probes

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N								
Transrectal		N								
Transvaginal		N								
Transurethral		N								
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Note1		N								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note1: Specification for "Other" :

Gastrointestinal tract, biliary, pancreatic duct and surround organs

Intraluminal ultrasound for upper airways and tracheobronchial tree

Urinary tract

Female reproductive tract:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011886

4.3.4 Indications for Use For
OLYMPUS UM-2R/3R Ultrasonic Probes

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P								
Transrectal		P								
Transvaginal		P								
Transurethral		P								
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Note1		P								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note1: 510(k) control numbers for the previously cleared indications
Gastrointestinal tract wall, biliary, pancreatic duct and surround organs. : K944610
Intraluminal ultrasound for upper airways and tracheobronchial tree: K982323
Urinary tract: K982610
Female reproductive tract: K001203
These previously control numbers were classified as the combination with the Olympus previous endoscopic ultrasound system EU-M30(K951994), EUS-20(K926514) and EU-M3(K882061). The feature, efficiency, and acoustic output of UM-2R/3R are not changed when they are combined with the new system EU-M60.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011886

4.3.5 Indications for Use for OLYMPUS GF UM130 Ultrasound Gastrovideoscope

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P								
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Note1		P								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note1: 510(k) control numbers for the previously cleared indications

Gastrointestinal wall, biliary, pancreatic duct, and surrounding organs: K971660

This previously control number was classified as the combination with the Olympus previous endoscopic ultrasound system EU-M30(K951994), EUS-20(K926514) and EU-M3(K882061). The feature, efficiency, and acoustic output of UM-2R/3R are not changed when they are combined with the new system EU-M60.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011886